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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/592,695	06/13/2000	Andrea G Cochran	P1762R1	7146

23552 7590 06/08/2005

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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/592,695	COCHRAN ET AL.	
	Examiner	Art Unit	
	Tersa Wessendorf		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7-12 and 20-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 7-12 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Status of Claims

Claims 1-3, 7-12 and 20-23 are pending and under examination.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/7/05 has been entered.

Claim Rejections - 35 USC § 112

Claims 1-3, 7-12 and 20-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the genus of the invention. The specification describes a cyclic peptide wherein position A3 is of defined structure without additional amino acid of 1-50 at either or both the N or C -terminus. The disclosure states that A3 residue, as define, is necessary to modify the other residues to obtain the different beta turns, hairpin, bulge or other turns. The specification does not describe A3 with any combinations of residues of length greater than four or five residues. More importantly, in combination with any number of residues at each or both ends of the peptide sequence. A written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula [or] chemical name of the claimed subject matter sufficient to distinguish it from other materials. University of California v. Eli Lilly and Col, 43 USPQ 2d 1398, 1405(1997), quoting Fiers V. Revel, 25 USPQ 2d 1601m 16106 (Fed. Cir. 1993). See also University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 (DC WNY 2003). The specific amino acids for A3 in combination with the general statements with respect to the different N or C amino acids will not be a

description of the huge scope of the present claims. The specification does not describe the kind, length or combination of amino acid residues in the short cyclic peptide that A3 can possess to exhibit any turns for the peptide. Likewise, there is no specific description of the cyclic peptide having the undefined residues at the N or C end. The Examples presented in the specification demonstrates how so much a change in one residue, especially for a short length peptide can result in a conformationally unstable peptide. The art is inherently unpredictable. It is not possible to predict that even with a predetermined sequence for said A3 with the N or C end the effect of other amino acid fragments. It cannot be ascertained from the undefined structure if one can reliably predict a conformationally or properly folded peptide. It is generally known that there are still no rules that have emerged that allow structure to be related to sequence in any simple fashion (even as applied to the actual compounds). In biotechnological invention one cannot necessarily claim a genus after only describing a single species because there may be unpredictability in the results obtained from species other than those specifically described. One may not preempt an unduly large field by the expedient of making broad prophetic statements in the specification and claim unless the accuracy of

such statements is sufficiently supported by well-established chemical principles or by sufficient number of examples. Applicants, at the time of filing, are deemed to have not invented species sufficient to constitute the genus by virtue of having disclosed a three species when the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed. In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 7-10 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wrighton et al (5,830,851) for reasons advanced in the last Office action on 10/29/04 and 10/06/03.

Response to Arguments

Applicants argue that Wrighton et al does not disclose a library of peptides comprising W at the position corresponding to M and W or L at positions corresponding to A4 of the present claims. Rather, in the preferred embodiments, X5 of Wrighton et al., which corresponds to A2 of Applicants' claims, specifies M, F, or 1. Applicants state that the fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that claim obvious citing In re Baird, 29 USPQ2d(Fed. Cir. 1994). A prima facie case of obviousness requires that one of ordinary skill in the relevant art would have been motivated to make the claimed invention as a whole i.e., to select the claimed species or subgenus from the disclosed prior art genus. MPEP 2144.08(II)(A)(4).

In response, the disclosure of Wrighton of a preferred embodiment does not preclude the other teachings present in the prior art. The prior art teachings should be taken as a whole. In considering disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also inferences which one skilled in the art would reasonably be expected to draw therefrom. In re Preda, 159 USPQ 342; In re DeLise 160 USPQ 806. In re Baird is inapplicable in the instant case. The claimed compound is not encompassed by the generic

formula of Wrighton as the claimed compound is a genus having A3 of no define amino acids except that it is 3-12 amino acids. Thus, the library isolated by Wrighton reciting specific residues for each of the different claimed residues is encompassed by the broad claimed compound library.

Applicants acknowledge that the Wrighton et al reference is directed to identifying agonists of EPO. But argue that Wrighton nowhere teaches or suggests that a peptide having W at position corresponding to A2 in applicants' claims would be advantageous in generating an EPO agonist, or an isolated library for presenting a beta turn hairpin structure or for any other reason.

In response, applicants' arguments appear contradictory. In one instance applicants state that Wrighton is directed to identifying agonists of EPO. While in the other instance that Wrighton does not teach for identifying agonists of EPO or for presenting beta turn hairpin structure or for any other reason. Applicants' arguments as to the beta turn is not commensurate in scope with at least claim 1, which does not recite said enhanced hairpin stability. Neither does the specification disclose that a peptide of undefined structure results, as claimed, produced enhanced stability. It would be within the ordinary skill in the art at the time the invention was made to determine the

stability of a known conformationally constrained peptide associated to the different turns a peptide assume. It is well known in the art that a peptide of a given primary structure assumes different turns e.g., beta for its stability.

Applicants argue that the claims are not limited only at positions A2 and A4 but at the other positions, as A1 and A5. Seq. ID. 89 of Wrighton has E at position corresponding to A1 as claimed. Seq. ID. 89 is not a species falling within the presently claimed genus.

In response, in considering the disclosure of Wrighton applicants appear to ignore the totality of Wrighton's teaching. Wrighton discloses that the prior art library, comprises, like the claimed library, the 20 naturally occurring amino acids at each of the positions as claimed. Wrighton has shown by the different isolated specific peptides that the various residues indeed can have any of the 20 naturally occurring residues at one position of the peptide sequence. For example, at position 2, as shown at ***e.g.,*** Table 7, col.3, Seq. ID 86 and 89 can be, inter alia, trp. While the residue at position 1 can be Trp or H or A (corresponding to X4). Thus, it is expected that since the different isolated specific peptide is obtained from a library of 20 natural amino acids hence, each of the positions within the cys-cys will have the claimed combination(s).

Applicants argue that the examiners' contention that one of skill would be motivated to substitute the A2 position of Wrigthon et al with all natural amino acids, including trp., because doing so would facilitate identification of lead compounds form the library is an "obvious to try" rationale for modifying the prior art reference.

In response, this is not an obvious to try since Wrighton positively discloses specific library as well as generic library. To pick and chose a residue that is within those disclosed in the prior art would be within the ordinary skill in the art. A library is well known in the art to produce compounds that lead to discovery of drug. This is the purpose, if not only the purpose, for which a library of compounds is employed. As held by the majority in Merck & Co. Inc. v. Biocraft Laboratories, Inc., 874 F.2d 804, 10 USPQ 2d 1843 (Fed. Cir. 1989), at 10 USPQ 2d 1846:

> That the '813 patent discloses a multitude of effective combinations does not render any particular formulation less obvious. See In re Corkill, 771 F.2d 1496, 1500, 226 USPQ 1005, 1008 (Fed. Cir. 1985) (obviousness rejection of claims affirmed in light of prior art teaching that "hydrated zeolites will work" in detergent formulations, even though "the inventors selected the zeolites of the claims from among "thousands of compounds").

Applicants' cite MPEP 21545(X)(B)(citing In re O'Farrel) in the context of a genus-subgenus relation.

In response, In re O'Farrell is inapplicable here since Wrighton does not teach only a genus but also species of the genus. The claimed library having no defined amino acids for A3 encompasses the genus or subgenus or species of Wrighton.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 7-12 and 20-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7, 9-11, 13 and 18-25 of copending Application No. 10/271,343 ('343 application). Although the conflicting claims are not identical, they are not patentably distinct from each other

because the instant claimed isolated library is but the cyclic peptide of the '343 application as the same compound formula (Seq. ID. 1) is being claimed. The difference resides only in the preamble which does not apparently affect the compounds having the same formula. The compound in the '343 application is actually a library, albeit not term as such, since there are different amino acids at the different positions of the cyclic peptide. Applicants should maintain a clear line of demarcation between the applications, as the two patents will issue out of the same claims, except in the wording of the preamble.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 11 and 12 are free of prior art.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be

reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
May 26, 2005